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EXAMINER	
BLANCHARD, DAVID J	
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1643	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/528,082	MOSCA, JOSEPH D	
	Examiner	Art Unit	
	DAVID J. BLANCHARD	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 October 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5,7,8 and 16-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,7,8 and 16-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 6 and 9-15 are cancelled.

   Claims 7-8 and 19 have been amended.

2. Claims 1-5, 7-8 and 16-26 are under consideration.

3. This Office Action contains New Grounds of Rejections

Rejections Withdrawn

4. The rejection of claim 7 under 35 U.S.C. 103(a) as being unpatentable over Hiserodt et al (U.S. 6,277,368 B1, filed 7/24/1997, cited on PTO-892 mailed 11/30/2007) in view of Wagner et al (Intervirology, 39(1)93-103, 1996) is withdrawn in view of applicants' arguments and amendments to the claims.

Rejections Maintained

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. The rejection of claims 1-5, 8, 16-20 and 23-26 under 35 U.S.C. 103(a) as being unpatentable over Hiserodt et al (U.S. 6,277,368 B1, filed 7/24/1997, cited on PTO-892 mailed 11/30/2007) in view of Wagner et al (Intervirology, 39(1)93-103, 1996) is maintained.

Hiserodt et al teach a method of treating cancer in a subject comprising inducing a cellular immune response involving T cells (i.e., "effector cell immune response") against cancer cells comprising administering tumor cells modified to express a cytokine and optionally altered to express additional cytokines, additional tumor-associated antigens, additional cell-surface molecules, such as adhesion molecules like ICAM-1, histocompatability antigens, or co-stimulation markers like B7-1 or B7-2 and the tumor cells may be autologous or allogeneic, are inactivated and wherein the cytokine-expressing cells are produced using a viral vector such as adenoviral and retroviral vectors (see entire document, particularly cols. 7-10, 15-19, and 21-23). Hiserodt et al do not specifically teach administering a non-infectious, biologically generated virus particle. This deficiency is made up for in the teachings of Wagner et al.

Wagner et al teach non-infectious, non-replicating virus-like particles (VLP) that self-assemble and provide a safe antigen delivery system for inducing a CTL response wherein the VLP can be expressed in host cells, rescued and purified from the cell culture supernatant in good quality and high yields and administration of VLP in subjects stimulates CD8+ CTL in the complete absence of adjuvants (see entire document, particularly pp. 94-95, 98-99, Fig. 4 and Table 1).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to produce a method for treating cancer in a subject comprising producing non-infectious, non-replicating VLP in the modified autologous or allogenic tumor cells of Hiserodt et al (e.g., expressing one or more tumor antigens in the presence of a co-stimulatory molecule, including B7-1 or B7-2) and administering the isolated/harvested non-infectious, non-replicating VLP for CTL induction and therapeutic benefit in cancer patients.

One of ordinary skill in the art would have been motivated to and had a reasonable expectation of success at the time the invention was made to produce a method for treating cancer in a subject comprising producing non-infectious, non-replicating VLP in the modified autologous or allogenic tumor cells of Hiserodt et al (e.g., expressing one or more tumor antigens in the presence of a co-stimulatory molecule, including B7-1 or B7-2) and administering the

isolated/harvested non-infectious, non-replicating VLP for CTL induction and therapeutic benefit in cancer patients in view of Hiserodt et al and Wagner et al because Hiserodt et al teach a method of treating cancer in a subject comprising inducing a cellular immune response involving T cells (i.e., "effector cell immune response") against cancer cells comprising administering tumor cells modified to express a cytokine and optionally altered to express additional cytokines, additional tumor-associated antigens, additional cell-surface molecules, such as adhesion molecules like ICAM-1, histocompatability antigens, or co-stimulation markers like B7-1 or B7-2 and the tumor cells may be autologous or allogeneic, are inactivated and wherein the cytokine-expressing cells are produced using a viral vector such as adenoviral and retroviral vectors and Wagner et al teach non-infectious, non-replicating virus-like particles (VLP) that self-assemble and provide a safe antigen delivery system for inducing a CTL response wherein the VLP can be expressed in host cells, rescued and purified from the cell culture supernatant in good quality and high yields and administration of VLP in subjects stimulated CD8+ CTL in complete absence of adjuvants. Therefore, one of ordinary skill in the art would have been motivated to modify the method of Hiserodt et al using the VLP for inducing a CTL response in cancer patients, since the VLP are non-infectious, non-replicating and provide a safe antigen delivery system for inducing a CTL response in the complete absence of adjuvant according to Wagner et al. The strongest rationale for combining references is a recognition, expressly or impliedly in the prior art or drawn from a convincing line of reasoning based on established scientific principles or legal precedent, that some advantage or expected beneficial result would have been produced by their combination. *In re Sernaker*, 702 F.2d 989, 994-95, 217 USPQ 1, 5-6 (Fed. Cir. 1983). Thus, it would have been *prima facie* obvious to one skilled in the art at the time the invention was made to produce a method for treating cancer in a subject comprising producing non-infectious, non-replicating VLP in the modified autologous or allogenic tumor cells of Hiserodt et al (e.g., expressing one or more tumor antigens in the presence of a co-stimulatory molecule, including B7-1 or B7-2) and administering the isolated/harvested non-infectious, non-replicating VLP for CTL induction and therapeutic benefit in cancer patients in view of Hiserodt et al and Wagner et al.

Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references.

Response to Arguments

A. Applicant states that claims 1-5, 7, 16- 18, 21, 23 and 24 all feature "virus-particle" which is distinct from a "virus-like particle" because a virus particle can be infectious and inactivated to become non-infectious as featured in claim 7. Applicant states that the cited prior art does not teach inactivating the virus-like particles of Wagner et al and as such is insufficient to meet the "virus particle"

B. Applicant argues that there is no evidence of record to show that the Hiserodt et al tumor cells and tumor cell lines were recognized as an equivalent of the virus-like particles of Wagner et al and vice versa. Applicant argues that the teachings of Hiserodt et al and Wagner cannot be combined because Hiserodt et al teach a combination of cells (e.g., the use of tumor cells and a cytokine producing cell, col. 7, lines 1-9) for producing an anti-tumor response, whereas Wagner et al teaches the use of an HIV-1 VLP to stimulate an anti-viral response. Applicant states that the instant rejection is based on impermissible hindsight reconstruction using the instant application as a guide.

C. Applicant argues that there is no reasonable expectation if success because there is no evidence of record that for the successful expression of a Wagner et al HIV-1 VLP in a Hiserodt et al tumor cell or tumor cell line. Further, assuming for the sake of argument that a VLP can be produced in a tumor cell or tumor cell line, there is still no evidence that a resultant VLP would have the features of the particles in the pending claims.

D. The instant invention reflects an advance over Hiserodt et al because (i) a virus or virus-like particle is able to act in place of the Hiserodt et al tumor cells and (ii) the particle can be used effectively without the Hiserodt et al cytokine producing cell. Thus, each advance is an unexpected result relative to the cited documents.

In response to A, with the exception of claim 7 as currently amended, applicants' distinction between a "virus particle" and a "virus-like particle" is not found persuasive. Claims 1-5, 8, 16- 18, 21, 23 and 24 recite a non-infectious, biologically generated virus particle and do not require the "virus particle" be inactivated. The instant specification does not define the terms "virus particle" or virus-like particle". Further, the ordinary skilled artisan would understand a virus particle to be a particle from a virus, which could be the nucleic acid, or a protein coat

given it's ordinary plain meaning and in the absence of any enlightenment by way of the specification. Thus, the virus-like particles of Wagner et al are merely one interpretation of a "non-infectious, biologically generated virus particle". Applicant is reminded that during patent examination, the pending claims must be given their broadest reasonable interpretation consistent with the specification. Applicant always has the opportunity to amend the claims during prosecution, and broad interpretation by the examiner reduces the possibility that the claim, once issued, will be interpreted more broadly than is justified. *In re Prater*, 415 F.2d 1393, 1404-05, 162 USPQ 541, 550-51 (CCPA 1969). The court explained that "reading a claim in light of the specification, to thereby interpret limitations explicitly recited in the claim, is a quite different thing from 'reading limitations of the specification into a claim,' to thereby narrow the scope of the claim by implicitly adding disclosed limitations which have no express basis in the claim." The court found that applicant was advocating the latter, i.e., the impermissible importation of subject matter from the specification into the claim.). See also *In re Morris,* 127 F.3d 1048, 1054-55, 44 USPQ2d 1023, 1027-28 (Fed. Cir. 1997) (The court held that the PTO is not required, in the course of prosecution, to interpret claims in applications in the same manner as a court would interpret claims in an infringement suit. Rather, the "PTO applies to verbiage of the proposed claims the broadest reasonable meaning of the words in their ordinary usage as they would be understood by one of ordinary skill in the art, taking into account whatever enlightenment by way of definitions or otherwise that may be afforded by the written description contained in applicant's specification.").

In response to applicants' arguments that Hiserodt et al is not equivalent to Wagner et al and therefore not combinable, applicant is reminded that "The test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference.... Rather, the test is what the combined teachings of those references would have suggested to those of ordinary skill in the art." *In re Keller*, 642 F.2d 413, 425, 208 USPQ 871, 881 (CCPA 1981). See also *In re Sneed*, 710 F.2d 1544, 1550, 218 USPQ 385, 389 (Fed. Cir. 1983) ("[I]t is not necessary that the inventions of the references be physically combinable to render obvious the invention under review."); and *In re Nievelt*, 482 F.2d 965, 179 USPQ 224, 226 (CCPA 1973) ("Combining the teachings of references does not involve an ability to combine their specific structures."). The idea that one of ordinary skill in the art would not have

been motivated by the benefits of the non-infectious, non-replicating virus-like particles (VLPs) of Wagner et al (e.g., VLPs self-assemble and provide a safe antigen delivery system for inducing a CTL response wherein the VLP can be expressed in host cells, rescued and purified from the cell culture supernatant in good quality and high yields and administration of VLP in subjects stimulated CD8+ CTL in complete absence of adjuvants) to modify the teachings of Hiserodt et al to produce a method for treating cancer in a subject comprising producing non-infectious, non-replicating VLP in the modified autologous or allogenic tumor cells of Hiserodt et al (e.g., expressing one or more tumor antigens in the presence of a co-stimulatory molecule, including B7-1 or B7-2) and administering the isolated/harvested non-infectious, non-replicating VLP for CTL induction and therapeutic benefit in cancer patients makes little sense. "A person of ordinary skill in the art is also a person of ordinary creativity, not an automaton."*KSR*, 550 U.S. at ___, 82 USPQ2d at 1397. "[I]n many cases a person of ordinary skill will be able to fit the teachings of multiple patents together like pieces of a puzzle."*Id.* Office personnel may also take into account "the inferences and creative steps that a person of ordinary skill in the art would employ."*Id.* at ___, 82 USPQ2d at 1396. In the instant case, Hiserodt et al teach a method of treating cancer in a subject comprising inducing a cellular immune response involving T cells (i.e., effector cell mediated immune response) against cancer cells comprising administering modified tumor cells using viral expression vectors and while Wagner teach HIV-1 VLPs for stimulating an anti-viral response, Wagner et al clearly conveys the concept of non-infectious, non-replicating VLPs that self-assemble and provide a safe antigen delivery system for inducing a CTL response (i.e., effector cell mediated immune response) wherein the VLPs can be expressed in host cells, rescued and purified from the cell culture supernatant in good quality and high yields and administration of VLP in subjects stimulated CD8+ CTL in complete absence of adjuvants. Thus, the teachings of Wagner et al would have suggested to one of ordinary skill in the art that non-infectious, non-replicating VLPs provide a safe antigen delivery system for inducing a CTL response in a subject, and VLPs can be expressed in host cells, rescued and purified from the cell culture supernatant in good quality and high yields, such that one of ordinary skill in the art would have been motivated to produce the non-infectious, non-replicating VLPs of Wagner in the tumor cells of Hiserodt et al for inducing an anti-tumor CTL response in cancer patients. Applicants' narrower inquiry that because Hiserodt et al is limited to

tumor cells and does not explicitly suggest VLPs and since Wagner et al is limited to HIV-1 VLPs for stimulating an anti-virus response that one of ordinary skill in the art would not be motivated by the advantages of VLPs to apply them to anti-cancer therapy, particularly where Hiserodt et al and Wagner et al teach that cell mediated immune responses (e.g., CTL response) are relevant for cancer and viral therapy applies the teaching-suggestion-motivation (TSM) test in an overly rigid and formalistic way. *KSR*, 550 U.S. at ___, 82 USPQ2d at 1391. "[I]n considering the disclosure of a reference, it is proper to take into account not only specific teachings of the reference but also the inferences which one skilled in the art would reasonably be expected to draw therefrom." *In re Preda*, 401 F.2d 825, 826, 159 USPQ 342, 344 (CCPA 1968).

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). As discussed supra, the instant rejection relies solely on the teachings and suggestions of Hiserdt et al and Wagner et al and as such is proper.

In response to C, Hiserodt et al teach that the tumor cells are modified by standard techniques to express a cytokine and optionally altered to express additional cytokines, additional tumor-associated antigens, additional cell-surface molecules, such as adhesion molecules like ICAM-1, histocompatability antigens, or co-stimulation markers like B7-1 or B7-2 and Wagner et al teach that VLPs can be expressed in host cells, rescued and purified from the cell culture supernatant in good quality and high yields. Thus, the art of Hiserodt et al and Wagner et al provide a reasonable expectation that the expression of VLPs in the tumor cells of Hiserodt et al would be successful. Applicant is reminded that obviousness does not require absolute predictability, however, at least some degree of predictability is required. Evidence showing there was no reasonable expectation of success may support a conclusion of nonobviousness. *In re Rinehart*, 531 F.2d 1048, 189 USPQ 143 (CCPA 1976).

Applicants' remarks that there is no evidence that the alleged VLPs would have a cellular membrane comprising "an MHC molecule that present on or more tumor-specific antigens" and "a co-stimulatory molecule" from Hiserodt et al tumor cell are acknowledged, however, as discussed supra Hiserodt et al teach the expression of tumor-associated antigens, additional cell-surface molecules, such as adhesion molecules like ICAM-1, histocompatability antigens, or co-stimulation markers like B7-1 or B7-2 in the tumor cells and as budding occurs by the VLPs from the tumor cells of Hiserodt et al, the VLP would necessarily incorporate the tumor antigens, surface molecule and co-stimulatory markers as a consequence of the budding process. For example, see Giguere et al (J. Virol. 78(12):6222-6232, June 2004), which provide evidence that the process of budding incorporates certain host-derived cell surface molecules into the viral particles.

In response to D, the above rejection sets forth the expectation that VLPs could be used for inducing an anti-cancer CTL response in cancer patients and as such this is an expected result. Further, the teachings of Wagner et al clearly indicate that VLPs can induce a CTL responses in subjects in subjects and in the complete absence of adjuvants. Thus, it would have been expected that the VLPs could be used without the additional cytokine(s). "Expected beneficial results are evidence of obviousness of a claimed invention, just as unexpected results are evidence of unobviousness thereof." *In re Gershon*, 372 F.2d 535, 538, 152 USPQ 602, 604 (CCPA 1967). Further, Applicant is reminded that objective evidence which must be factually supported by an appropriate affidavit or declaration to be of probative value includes evidence of unexpected results, commercial success, solution of a long-felt need, inoperability of the prior art, invention before the date of the reference, and allegations that the author(s) of the prior art derived the disclosed subject matter from the applicant. See, for example, *In re De Blauwe*, 736 F.2d 699, 705, 222 USPQ 191, 196 (Fed. Cir. 1984). The arguments of counsel cannot take the place of evidence in the record. *In re Schulze*, 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965).

9. The rejection of claims 1, 19, 21 and 22 under 35 U.S.C. 103(a) as being unpatentable over Nawrocki et al (Cancer Treatment Reviews, 25:29-46, 1999, cited on PTO-892 mailed 8/29/2008) in view of Wagner et al (Intervirology, 39(1)93-103, 1996) is maintained.

Nawrocki et al teach a method of treating cancer in a subject comprising inducing a cellular immune response involving T cells (i.e., "effector cell immune response") against cancer cells comprising administering autologous non-tumor cells (e.g., dendritic cells, fibroblasts, monocytes) modified using a retroviral, non-viral lipid, or adenoviral gene delivery system to express a tumor antigen, a B7 co-stimulatory molecule and a cytokine (see entire document, particularly abstract, pp. 38-41). Nawrocki et al do not specifically teach administering a non-infectious, biologically generated virus particle. This deficiency is made up for in the teachings of Wagner et al.

Wagner et al have been described supra.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to produce a method for treating cancer in a subject comprising producing non-infectious, non-replicating VLP in the modified non-tumor cells of Nawrocki et al (e.g., expressing a tumor antigen, a B7 co-stimulatory molecule and a cytokine) and administering the isolated/harvested non-infectious, non-replicating VLP for CTL induction and therapeutic benefit in cancer patients.

One of ordinary skill in the art would have been motivated to and had a reasonable expectation of success at the time the invention was made to produce a method for treating cancer in a subject comprising producing non-infectious, non-replicating VLP in the modified non-tumor cells of Nawrocki et al (e.g., expressing a tumor antigen, a B7 co-stimulatory molecule and a cytokine) and administering the isolated/harvested non-infectious, non-replicating VLP for CTL induction and therapeutic benefit in cancer patients in view of Nawrocki et al and Wagner et al because Nawrocki et al teach a method of treating cancer in a subject comprising inducing a cellular immune response involving T cells (i.e., "effector cell immune response") against cancer cells comprising administering autologous non-tumor cells (e.g., dendritic cells, fibroblasts, monocytes) modified using a retroviral, non-viral lipid, or adenoviral gene delivery system to express a tumor antigen, a B7 co-stimulatory molecule and a cytokine and Wagner et al teach non-infectious, non-replicating virus-like particles (VLP) that

self-assemble and provide a safe antigen delivery system for inducing a CTL response wherein the VLP can be expressed in host cells, rescued and purified from the cell culture supernatant in good quality and high yields and administration of VLP in subjects stimulated CD8+ CTL in complete absence of adjuvants. Therefore, one of ordinary skill in the art would have been motivated to modify the method of Nawrocki et al using the VLP for inducing a CTL response in cancer patients, since the VLP are non-infectious, non-replicating and provide a safe antigen delivery system for inducing a CTL response in the complete absence of adjuvant according to Wagner et al. The strongest rationale for combining references is a recognition, expressly or impliedly in the prior art or drawn from a convincing line of reasoning based on established scientific principles or legal precedent, that some advantage or expected beneficial result would have been produced by their combination. *In re Sernaker*, 702 F.2d 989, 994-95, 217 USPQ 1, 5-6 (Fed. Cir. 1983). Thus, it would have been *prima facie* obvious to one skilled in the art at the time the invention was made to produce a method for treating cancer in a subject comprising producing non-infectious, non-replicating VLP in the modified non-tumor cells of Nawrocki et al (e.g., expressing a tumor antigen, a B7 co-stimulatory molecule and a cytokine) and administering the isolated/harvested non-infectious, non-replicating VLP for CTL induction and therapeutic benefit in cancer patients in view of Nawrocki et al and Wagner et al.

Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references.

Response to Arguments

Applicant argues as above against the rejection of Hiserodt et al in view of Wagner et al with the exception that the instant rejection relies upon the non-tumor cells of Nawracki et al in place of the tumor cells of Hiserodt et al and the examiner's remarks above apply here as well and are incorporated herein by reference.

New Grounds of Rejections

19. Claim 7 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter, which was not described in

the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

The response filed 10/19/2009 has introduced NEW MATTER into the claim. As presently amended claim 7 recites that the non-infectious particle is an inactivated intact virus particle that was infectious. The response noted that claim 7 has been revised to more explicitly state an inherent feature of the claim, however, the response did not point out where support for presently amended claim 7 could be found in the originally filed disclosure. Although the PTO has the initial burden of presenting evidence or reasons why persons skilled in the art would not recognize in the disclosure a description of the invention defined by the claims, when filing an amendment an applicant should show support in the original disclosure for new or amended claims. See MPEP 714.02 and 2163.06 ("Applicant should therefore specifically point out the support for any amendments made to the disclosure."). Example 1 of the specification discloses that the gag-expression system dependent on HIV-tat activation of the HIV-LTR in the absence of HIV-env so that only virus-like particles composed of the gag protein would be elaborated into the culture and that this provides a mechanism by which the biological particle/carrier technology can be performed with non-infectious viral particles, rather than infectious particles that required UV chemical inactivation before use. The instant disclosure does not adequately describe the administration of non-infectious inactivated intact virus particles that were infectious and which comprise an MHC molecule and a co-stimulatory molecule for the treatment of cancer in patients. In contrast, the context of the as filed disclosure is primarily directed towards the generation of non-infectious viral-like particles as biological particles/carriers, particularly HIV-1 gag particles capable of inducing a T cell response. It is noted that there is no disclosure of the administration of the HIV-1 gag particles in a subject for treating cancer and the examples provided appear to be prophetic in nature.

As presently amended claim 7 now recites limitations, which were not clearly disclosed in the specification as filed, and now change the scope of the instant disclosure as filed. Such limitations recited in presently amended claim 7, which did not appear in the specification, as filed, introduce new concepts and violate the description requirement of the first paragraph of 35 U.S.C 112. Applicant is required to provide sufficient written support for the limitations recited

in present claim 7 in the specification or claims, as filed, or remove these limitations from the claims in response to this Office Action.

10. No claim is allowed.

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Blanchard whose telephone number is (571) 272-0827. The examiner can normally be reached at Monday through Friday from 8:00 AM to 6:00 PM, with alternate Fridays off. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, can be reached at (571) 272-0832.

The official fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/David J. Blanchard/
Primary Examiner, A.U. 1643